1 2 3 4 5	SOUTHERN WEST PA CASE NO. 2 IN RE: ZANTAC (RANIT)	ATES DISTRICT COURT DISTRICT OF FLORIDA LM BEACH DIVISION 20-md-02924-ROSENBERG IDINE) . West Palm Beach, FL . March 18, 2022 .
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8	BEFORE THE HO	HEARING (through Zoom) DNORABLE BRUCE REINHART
9	UNITED STAT	TES MAGISTRATE JUDGE
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1 THE COURT: Hello, everybody. This is Case Number 2 20-2924, In Re: Ranitidine Zantac Product Liability Litigation. We are here today for a discovery hearing. 3 4 Let me begin by recognizing the parties. I will start 5 with counsel for the Plaintiffs. 6 MR. NIGH: This is Daniel Nigh on behalf of the 7 Plaintiffs. 8 MS. FINKEN: Good afternoon, Judge Reinhart, Tracy 9 Finken on behalf of Plaintiffs. THE COURT: Good afternoon. On behalf of the brand 10 Defendants. 11 12 MR. SHEEHAN: Tom Sheehan, your Honor, on behalf of 13 the brands. Thank you. 14 THE COURT: Hold on a second, we have a couple more 15 people in the waiting room. Let's admit them. 16 Okay. We are here on the Defense's request for 17 additional time to depose the Plaintiffs' general causation 18 experts. I received the Defense's motion at Docket Entry 5396 19 requesting an additional, by my count, 17 hours to depose five 20 experts, and I received the Plaintiffs' opposition at Docket 21 Entry 5407. 22 Were there any other filings or submissions that I have not mentioned, from the Plaintiffs? 23 2.4 MR. NIGH: No, your Honor.

THE COURT: From Defense?

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MR. SHEEHAN: No.

THE COURT: Great. It is the Defense's motion, so let me hear first from Mr. Sheehan.

MR. SHEEHAN: Thank you so much for hearing us today, your Honor. I will try to be succinct, but I do think there are a few things that need to be laid out just to frame the issues here.

So, the expert opinions that are being offered at this stage in the litigation by design relate to the threshold issue of general causation. Does Ranitidine, when used therapeutically, cause the specific cancers being alleged, five cancers here. That is, in essence, the question that we are dealing with in these expert reports.

Cancer causation, as you might imagine, is a complicated subject. Cancer is an extraordinarily heterogeneous disease, and here in this MDL we have five different types of cancer that each have their own different sub types of cancer in five different organ systems, and each of these types of cancer has its own sort of profile, if you will, what cell type is at issue, the unique characteristics of the cancer, the genetic profile of the cancer, different risk factors, different causes.

So, the bottom line is, it is scientifically dense, it is scientifically complicated to figure out reliably what causes any particular type of cancer. Irrespective of

Ranitidine, as you might know, the scientific community has been grappling with these issues for decades and decades.

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Now, the Plaintiffs served 12 expert reports in support of their position. As you know, they are long, they are complex, and I don't think anybody can reasonably argue with that characterization.

So, after we got the reports we reviewed them carefully and we realized, hey, we are going to need more than seven hours with some of these folks, so we went to the Plaintiffs, we asked. It took a little time to coordinate, get together to get a final response, but at the end of the day, they said, no, we are not giving you any more time.

That is why we are here. We are asking for targeted additional time for five out of the 12 general causation expert reports that were served, and we believe our request is warranted under Rule 30 and Rule 26, and that moreover, our request is quite reasonable for a number of reasons.

First, as I mentioned, nobody disputes that cancer causation is complex. It involves damaged DNA at the cellular level, cell growth factors, cell programming, DNA repair mechanisms, to name just a few topics, at sort of the biological and cellular level of cancer causation.

The evidentiary base upon which the Plaintiffs' experts purport to rely involves in vitro studies, essentially test tube studies that test different attributes of various

compounds at various concentrations relating to topics like mutagenesis and chemical nitrosation. It involves animal studies of various species looking at the so-called add me outcomes, that's absorption, distribution, metabolism, excretion of various compounds in various animal systems. It involves animal studies of, frankly, cancer outcomes, the actual cancer end point in different organ systems in these animals, involving species with varying relevance, if any, to humans.

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Of course, the evidentiary base here also involves human data, from the Defense perspective, probably the most pertinent data. Those data also involve these add me outcomes, absorption, metabolism, that sort of thing. It involves human data relating to the expression of enzymes in different tissue beds that are required to even metabolize NDMA to have any sort of harmful effect on DNA, and naturally it involves cancer outcomes in humans, which is after all what this litigation is all about.

Even those studies, the epidemiology studies of cancer outcomes in humans, have different sort of buckets, if you will. They include studies of various dietary exposures, whether the NDMA, whether the nitrites, whether the nitrates, occupational exposures to the rubber workers that you heard about at Science Day, and finally, studies of folks that took Ranitidine itself, the drug at issue here, and whether those

folks had any increased risk of cancer.

I could go on and on, but I just wanted to give you a sense of the breadth and the complexity of the issues that are at play here. Because of that complexity, we got massive reports. We are not complaining about the massive reports, we detailed that in our brief, hundreds upon hundreds of pages, hundred upon hundreds of references purportedly supporting the opinions that are being proffered.

In particular, for the five experts where we are asking for limited additional time, and to add just another layer here of the complexity for your Honor's consideration, there are original calculations in these reports that were done for the purposes of supporting the litigation opinion.

For example, Dr. Salmon, he is a toxicologist that is being offered by the Plaintiffs, he does his own calculations of dose that he extrapolates from various studies, and then does dose response analyses that are his own calculations within the body of his Rule 26 report.

Dr. Najafi as well, as you know, he was hired by the Plaintiffs to do original testing, and he did. He did all kinds of testing, various experiments, whether in a simulated gastric context, whether testing the tablets themselves under various conditions relating to sun, shade. All the things that are in Dr. Najafi's report are original, and we wouldn't have seen them prior to getting his Rule 26 report.

These were calculations and experiments done for the purpose of supporting the opinions that are being offered in the litigation, and I don't have to go into chapter and verse I hope, but whatever the burden is for complexity of issues and scope of opinions that warrants additional deposition time, I think that burden has been met in this litigation for these five experts.

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I want to just briefly address some of the arguments made by the Plaintiffs in their opposition.

First, the Plaintiffs say we are trying to modify the Court's pretrial orders. I don't think that is a fair characterization. PTO 65 does not speak to the length of any specific deposition; rather, deposition length is governed by Rule 30(d)(1), which permits additional time to fairly examine a deponent where warranted. Here, we think it is warranted.

Plaintiffs also reference PTO 54, which is the deposition protocol. PTO 54 allows the seven-hour presumptive limit to be extended by Court Order or stipulation. We asked for a stipulation, obviously there was no agreement, and that is why we are here. We are asking you now for five specific witnesses out of the 12 Rule 26 expert reports that were served.

To the extent that Plaintiffs are trying to conflate 30(b)(6) witnesses with expert witnesses, honestly I think it is apples and oranges. The Plaintiffs' experts were hired

specifically to provide expert reports and testimony in this litigation, and as I have just detailed for your Honor, we believe our requests for the five experts where we are seeking additional time are more than justified.

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Second, the Plaintiffs suggest that our ask is premature and that we should go take the depos, get to the seven-hour limit and then ask for more time. I thought about that, and honestly, I am not sure I can't think of a more inefficient way to go about doing this.

We are asking up front now because we have already carefully considered all 12 Plaintiff expert reports, and we are not asking for more time for all. We are not asking for a blanket extension of deposition time. We are asking for additional time, limited additional time for five experts precisely because we have already determined, based on the complexity and breadth of the opinions, that we are going to need the additional time.

Getting the time worked out now will actually avoid disruptions later. If we do it the way the Plaintiffs suggest, we are going to be asking for more time, there is going to be a dispute, we are going to have to get a ruling, and then you are really talking about screwing up the schedule about extensions to the expert discovery deadline, about extensions to Daubert briefing, all the stuff that flows from the expert depositions.

Third, the Plaintiffs make an argument that I think

boils down to something like this: The longer the report, the less you need a deposition. Respectfully, honestly, I just don't think that is realistic. For a case like this, longer and more complex reports require additional time to understand and explore the bases of the expert opinion.

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I was thinking about this last night, and I don't know if this is a good analogy or not a good analogy, but it's tax season. We are all doing our taxes. Just because the tax code is very long and complex doesn't mean it is easy to understand and apply, right? We all know this. They have it a little bit backwards here, I think.

I would add that just because a report is long and cites to lots of things, it doesn't necessarily mean it is complete, which is actually what is required under Rule 26. The five experts at issue here cite to hundreds of references throughout their reports, but often they don't examine some of the references in any meaningful way, which is exactly why we need to be able to explore that, and it warrants additional time to understand why they are citing to things without an appropriate explanation or why it supports the proposition for which it is being cited.

One of the cases, one of the primary cases that the Plaintiffs cite is this Florida automobile case, so we pulled that case. As far as we can tell, it doesn't make any ruling on length of depositions; rather, the Court there was deciding

whether the Plaintiff in expert reports were complete under Rule 26, and it decided that they weren't despite their length.

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Finally, the Plaintiffs say that our reliance on the Valsartan litigation is misplaced. Quite frankly, we disagree with them. We think it is very instructive and illustrates that where the opinions being proffered are lengthy and complex it warrants more deposition time, not less. Here, the scientific literature on Ranitidine and cancer outcomes is far more robust than that for Valsartan and cancer outcomes.

So, your Honor, we think we have clearly met the burden for good cause for additional deposition time with these five experts, and we respectfully ask that you grant our request. Thank you so much.

THE COURT: Thank you, Mr. Sheehan. I will give you a chance to respond after I hear from the Plaintiffs.

Mr. Nigh, let me hear from you.

MR. NIGH: Thank you, your Honor. Daniel Nigh on behalf of the Plaintiffs.

Your Honor, I wanted to start by first explaining that I am co-lead counsel in the Valsartan MDL litigation, so I know those issues well. That is the primary case that the Defendants cited to, so I am going to talk about some of those issues and distinguish what has happened in Valsartan versus here in Zantac.

What we know is, if we go over seven hours of record

time the depositions will take two days. In Valsartan, these depositions that we had ten hours of record time, every single one of them took two days, both on the Defendants' side and the Plaintiffs' side. So there is no doubt that it is going to create certainly more time into what is already a crowded schedule.

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First, as we talk about what happened in Valsartan, the Defendants had certain arguments that we don't have here. One of the main arguments that they raised in terms of the amount of time that they should be able to examine the experts was precisely the amount of the time that the Plaintiffs had to examine their 30(b)(6) witnesses.

What we know in terms of 30(b)(6) witnesses here in Zantac is even more complicated than what it was in Valsartan, but in Valsartan we had two and a half days, even one witness that was three days, to examine those 30(b)(6) witnesses because we got to examine them Rule 30(b)(6), and then some of them had a facts scenario. We are talking 17 and a half hours that was given for 30(b)(6) witnesses in Valsartan.

Defendants used that and said, well, if they are allowed to have 17 and a half hours, why can't we have at least ten hours of deposition time for their experts? That was a major push in terms of ordering that they could have ten hours for those expert depositions.

On the flip side, in this litigation we have 30(b)(6)

with either clinical trials, animal studies, scientific studies. I can go on and on with a long list of complexities that these 30(b)(6) witnesses had, that we took depositions here, hundreds of thousands of pages of documents, and the Defendants refused to give us additional time. Those depositions took seven hours, we were efficient in those depositions, and we got them done in seven hours.

So, in that same analogy, unlike in Valsartan where we had plenty of time in terms of taking these depositions on these key scientific complex issues, we did not here. So, looking at that, we don't believe that that argument that they latch on to, that they had in Valsartan applies here.

And frankly, they should be able to get these expert depositions done in seven hours to the extent we were able to take those very complicated 30(b)(6) witnesses in seven hours.

Second, in Valsartan, the number of expert witnesses that we disclosed on the Plaintiffs' side was five and nine on the Defense side, so a total of 14 experts. Right now, for Zantac, we have 12 on the Plaintiffs' side and 13 on the Defendants' side, so a total of 25 experts, nearly double the number of experts.

On the other side, when we talk about complexities in Valsartan, as we discussed, we had over ten cancers that passed Daubert in Valsartan and went through. Here we are only

alleging five cancers. So, in terms of complexity, we had double the number of cancers in Valsartan compared to here. Those are a lot of the things that distinguish it.

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Coming back to the scheduling order, as part of our scheduling order, when we agreed that each expert would get three days for deposition there was no discussion of two consecutive days, and it was not envisioned that these depositions would take two days. So it would create scheduling havoc to now rewrite the scheduling order and try to get an extra consecutive day for each of these experts on what is already a crowded calendar for the next two months.

Finally, I will turn to the pages, because the page count seems to be the majority of the Defendants' arguments that these are long reports, and we don't believe that is a valid reason to give more than seven hours.

The Defendants' experts and the Plaintiffs' experts are addressing the same issues. They are the same facts, similarly, the same scientific theories, so more pages really means that the experts' bases are thoroughly explained in the expert report. That is how the analogy goes. There are not two different tax codes that the Plaintiffs presented and the Defendants presented, they're based on the same.

Here, we have the same issues, same theories, same explanations, except Defendants' experts have a different view, and they give much less bases in their expert reports, so we

actually have to more thoroughly examine what is the bases for those, whereas our expert reports lay it out. It is very clearly explained, so there is less of a reason to have to explore our expert report topics because they are thoroughly explained in the expert reports.

That is all I have. Thank you.

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THE COURT: Thank you. I have one question though.

You say if the Defendants are allotted ten hours, you have to find consecutive depositions dates. Why? Most of the depositions in this case are being done by Zoom, they are being done remotely. Dr. Najafi, if he is available for seven hours tomorrow and three hours next Tuesday, why can't that be done? And why couldn't you do the additional three hours for Dr. Najafi in the morning and the other three hours for Dr. McTiernan in the afternoon? Why can't those be arranged that way?

MR. NIGH: I don't think it is impossible to do it that way, but I do think that it is an advantage for the questioner because they can take that transcript and look at it, they can examine it, the additional time to be able to think about what are all the additional questions we want to come back and ask looking at what was answered in the deposition.

And I will say we had that same scenario in Valsartan and both sides had to be faced with the same task and in every

single situation they figured out that they would have to do it in consecutive days.

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THE COURT: Other than that, not to minimize, but other than the concern about just the compressed schedule and having the logistics of scheduling in that additional time, and assuming what I have always done in this case, which is if I grant the Defendants' motion to give them additional time, I will give the Plaintiffs the same time when it comes time for the Defendants' experts, what is the prejudice to the Plaintiffs if I allow the additional time?

MR. NIGH: The prejudice is more so on the scheduling, and simply that there are 25 experts in two months. That is probably the gist of it, and then we would, in order to avoid the prejudice of that, having a break and disadvantage, that we would need to find consecutive days.

THE COURT: I appreciate that. Thank you very much.

Let me go back to Mr. Sheehan and let him respond if you'd like.

MR. SHEEHAN: Sure. Really briefly, your Honor, I think, first, we would be happy to work with the Plaintiffs, we can find consecutive days, nonconsecutive days. We will do it however it works. This is not just the number of the pages, as I think I illustrated to you, it is really about the complexity of the issues. We have thought about it, legitimately thought about it hard, had conversations internally, how much time do

you need to properly take these depositions, and that is exactly what we laid out for you in our motion.

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Now, with respect to the idea of, you know, this was worked out before and -- of course the PTOs were worked out before. At the time, I think everybody presumes, hey, we can get it done in seven hours, but you don't know until you see the reports. Imagine if we had said in advance we are going to need two days with your experts, they would have said, wait until you see our reports, you can get it done in one day.

The whole process here is looking at the reports, evaluating what you need, and then asking if we can get more time and then ultimately coming to you.

I think it is a little -- it just doesn't make sense to go back to the PTO and say, you knew -- you could have said then that you needed more time with these five experts out of the 12 that we are asking for.

And I think with respect to the 30(b)(6)'s, actually there was more time for 30(b)(6)'s that was negotiated with various Defendants. It wasn't a blanket, no, you can't have more time. That did occur, and those negotiations happened and in certain instances more time was permitted by agreement.

That is all I have, your Honor.

THE COURT: Thank you very much.

MS. FINKEN: Your Honor, can I respond to one point that Mr. Sheehan made, if that is okay?

THE COURT: Of course.

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MS. FINKEN: Tracy Finken on behalf of Plaintiffs.

Your Honor, going back to the PTO 65 issue, you are well aware of this, but I just want to make this point. It was a heavily negotiated order by both sides, and when we negotiated it, and I was one of the people negotiating it, we contemplated this very expedited schedule on the spring expert discovery schedule with the express point that there would be one day contemplated for expert depositions.

It is in the order, it is in the order that we would provide the three possibilities up front so that we could schedule accordingly. There was never any contemplation of doing depositions for more than one day of each expert knowing that we had a very, very condensed schedule and that we would have a very limited amount of time to get all of the expert discovery done, and that we needed to get done to get the Daubert hearings teed up for when Judge Rosenberg wanted them teed up in the summer.

It is something that was contemplated and built into the schedule that we have the way that it was. I do not think that is a small point, it is something that the parties considered and did this expedited schedule jointly and agreed upon going forward.

25 expert depositions for one day in the time that we have is a lot. If we are adding two days for some of those

experts now going forward it is going to be really, really tight to get that done in a meaningful time to get the Daubert motions teed up the way that we need to for Judge Rosenberg's schedule.

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THE COURT: Let me ask you, again, no disrespect, but it is not a heavy lift to defend the deposition. All you can do is object on the basis of the form of the question anyway, you can't lodge substantive objections.

You have a lot of lawyers on this case. If you have to double stack some depositions, again, what is the prejudice to the Plaintiff defending the deposition if you have to double stack a deposition and you cover one and another LDC member covers the other?

MS. FINKEN: Your Honor, we are already double stacked and triple stacked, and quadruple stacked, I can tell you that. Having looked at the schedule yesterday, we are double and triple stacked already with the experts that need to be deposed in this period of time with taking Defense expert depositions and defending our experts as well. So, it already is double and triple stacked.

So, just so you are aware of that, it is already done that way.

MR. NIGH: Your Honor, just to highlight here, too -THE COURT: Hold on. Go ahead, Mr. Nigh.

MR. NIGH: Daniel Nigh again.

Just to reiterate, every single one of the dates that the Defendants offered, except for one expert that they offered some April dates, all the rest of them were in May. I spoke to two a month, but it is really May, and really the last two weeks of May where we have multiple experts, you know, really over stacked. And these experts that they have asked for for two days, some of those are right in that same time frame, the two-week time frame. That is what really makes this -- causes a congestion, so to speak.

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THE COURT: All right. Let me ask Mr. Sheehan.

Mr. Sheehan, why don't you respond to that specific point? I don't know that you directly addressed that.

MR. SHEEHAN: With respect to whether the schedule is too congested, is that the ask?

THE COURT: Yes. I hear Mr. Nigh and Ms. Finken saying even if we wanted to be accommodating, given the dates that we have scheduled and the limitations set by Judge Rosenberg, this is just an impossibility to find the extra time that is going to be needed.

MR. SHEEHAN: I don't think that is true necessarily. We have three days that have been offered for various experts, and we are asking for limited time for specific experts, for five out of the 12. We are not asking for two deposition days for 12 experts, and I imagine the Plaintiffs are not going to be asking for two additional days for the 13 Defense experts.

I think it should be possible to find, whether they are consecutive or not consecutive, or whether an expert wants to consider -- I have done ten-hour depositions in one day, I have done it before. It is not like that is an impossibility. It is a long day for sure, but it can be done. I don't think the schedule itself should dictate whether or not additional deposition time is warranted to properly examine the bases of the expert opinions that are being offered, which is our primary argument here, your Honor.

THE COURT: All right. Thank you.

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So the issue -- let me start with a couple of things. First of all, while I hear the argument about the PTOs, I think the PTOs, at least on their terms, all contemplate that any party can seek additional time from the Court.

While I recognize Ms. Finken's point, and I remember it well, that this was a very carefully negotiated issue, I do recognize that on its face the PTO does not preclude the Defendants from asking for what they are asking for. The operative rules that I have to apply are Rule 30(d), and also Rule 26, because any discovery request has to be gauged against the standards of proportionality in Rule 26.

So the question is, is there good cause for the additional time, and do the other proportionality factors weigh in a way that I should allow the additional time?

So, first of all, I am not persuaded that there have

to be consecutive days of deposition here. I hear what Mr. Nigh and Ms. Finken are saying, but I am not sure that a lawyer being able to be better prepared because they can go back and review the early transcript to ask better questions in the second half of the deposition is improper.

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The purpose of the deposition is to elicit evidence and elicit information, so I don't consider that an unfair tactical advantage necessarily. It may be mean the person is better prepared and more streamlined. So, while I hear that, I don't believe that consecutive days are necessary to conduct these depositions, which means that you could stack the extra time on the same day if that's what I decided I should allow you to do.

Also, while I am appreciative and it's certainly informative to know about the Valsartan litigation, I don't know that case, I don't know what was going on in that case, and I'd have to rule independent of that particular case. Like I said, it is informative, but not persuasive, candidly.

So, I think, as I said previously, looking at the Rule 26 factors, obviously general causation is an extraordinarily important factor in this case, we have discussed that from day one. So, to the extent there is — one of the proportionality factors is whether the issue under dispute is important to the litigation. This is extraordinarily important to the litigation.

Then the question is, is the evidence that is trying to be elicited here important to proving that fact? Obviously it is. We have spent the better part of two years building up to this moment, what we have done. All the discovery hearings that I have ruled on, all of the hundreds or thousands of hours that you all have put in is building up to Daubert and to Judge Rosenberg being able to rule on general causation, which I think everybody agrees the rulings on Daubert are going to have a substantial influence on where this litigation goes, if this litigation proceeds and if it settles, and how quickly it moves forward and all those things. So this is an extraordinarily important issue.

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I do find there is good cause for the additional time that the Defendants are asking for. I think, given the investment that all of us have made in getting to this point, it would be ill advised for me and certainly not in the interests of the just, speedy, expensive and fair resolution of this case to truncate this sort of inquiry.

To the extent I am going to err on the side of allowing a more robust discovery at the general causation stage, I think this is certainly the time to do so.

I am going to grant the Defendants the additional time that they have asked for. I am going to grant the Plaintiffs the same time when it comes time for the Defense's experts if the Plaintiffs want to take that time.

So the question then becomes -- I am granting the Defendants three additional hours for Dr. Salmon, three additional hours for Dr. Najafi, three additional hours for Dr. Mormon, three additional hours for Dr. Panigrahi, and five additional hours for Dr. McTiernan. I will grant the Plaintiffs an additional 17 hours how they choose to allocate it, if they choose to allocate it, as to the Defense experts.

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With that, not waiving any objections that the parties may have to the Court's rulings, let me turn first to the Defense. Mr. Sheehan, any clarifications or modifications of the order that you would request at this time?

MR. SHEEHAN: No, your Honor, I think that is clear. Thank you very much. If anything comes up we will ask for your guidance.

THE COURT: Let me suggest one other question. I think the Plaintiffs make a fair point, the better -- I know many times in this case I have told you to take this incrementally, go take the deposition and see if you really need the additional time. I recognize I am deviating today from that normal practice.

The reason I am doing it is in part because I do recognize the compacted schedule that we are facing and I think any time that would be spent teeing up, litigating, and arguing whether Defendants should get additional time is better spent just using that time to take these depositions, given, as I

said earlier, my strong feeling that at this stage of the 1 litigation I am going to err in favor of more robust discovery. 2 3 I did want to address that argument because I think it is a fair argument, but I wanted to explain why I was deviating 4 5 from what I have done in the past. 6 Let me turn to the Plaintiffs, not waiving any 7 objection that you may have to the ruling I have made, do you 8 seek any clarifications? 9 MR. NIGH: No clarifications, your Honor. Thank you. THE COURT: Thank you all very much. I wish everyone 10 a good weekend. We'll be in recess. 11 12 MS. FINKEN: Thank you, your Honor. 13 (Thereupon, the hearing was concluded.) 14 15 I certify that the foregoing is a correct transcript 16 from the record of proceedings in the above matter. 17 18 March 20, 2022 Date: 19 /s/ Pauline A. Stipes, Official Federal Reporter 20 Signature of Court Reporter 21 22 23 2.4 25

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